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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,320

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Bernd Meyer

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K.F. ROSS P.C.

5683 RIVERDALE AVENUE

SUITE 203 BOX 900

BRONX, NY 10471-0900

EXAMINER

DANEGA, RENEE A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,320	Applicant(s) MEYER ET AL.	
	Examiner RENEE DANEGA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 3 and 8-11 are objected to because of the following informalities: Claims 3 and 8-11 are device claims depending from claim 1 which has been amended to claim a method. Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3 and 5 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni et al. (US 5191896) in view of Demand (US 4759712).
 - Regarding claim 1, Gafni teaches a method of measuring sensory threshold which is used in the determination of sensory disorders in which a device is provided to measure thermal sensitivity using a plurality of methods such as method of limits, which is known to be a method of increasing a stimulus is detected or lowering it until no longer detected, thus correlated to a perception of temperature (column 1, lines 35-50). Gafni teaches using a skin temperature sensor (22) to communicate body surface temperature with the computer (figure 1, column 2, lines 50-54). Gafni doesn't teach directing an air stream onto the measurement area. However, Demand teaches a nerve sensitivity measuring apparatus,

which uses pressurized fluid defined to be air (column 6, lines 29-32). It would have been obvious in view of Demand to use an apparatus that produces forced air in Gafni's method in order to remove possible influences on perception of using solid object in contact with the test area.

- Regarding claims 2-3, Gafni teaches using two time periods during which the stimulus is present and is not present (column 4, lines 13-15). Gafni is silent as to moving the test element so it is presumed to be at a constant position. More important, there are only two alternative ways to position the device relative to the measurement point, one is constant and the other is variable. Absent any showing of unexpected benefit, it would have been obvious in the art to either position the device at a constant or variable spacing as such is taken to be well within the purview of choice in the art. Moreover, varying the distance would have been an obvious test method to try in order to test for nerve sensitivities.
- Regarding claim 5, Gafni uses a skin temperature sensor to send information back to the computer to influence the test protocol (column 2, lines 50-54).
- Regarding claim 9, Demand's temperature display (82) would be capable of indicating a perceived temperature and feedback (52) of temperature sensor (50) would allow for determining of perceived temperature (Figure 1).

- Regarding claim 10, Demand's device has a portable probe, which would be capable of being moved varying distances from the target (Figure 1).

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni and Demand as applied to claim 1 above, and further in view of Potter et al. (WO 03/000124).

- Regarding claim 4, Gafni and Demand don't teach using 3 superimposed light beams for determining the spacing. However, Potter, drawn to a measuring probe for a human body, teaches using two intersecting light beam for measuring the distance or spacing between the probe and the human body. Moreover, one in the art would have reasonably recognized and appreciated that more than two converging beams could be used effectively to calculate a measurement of a distance in space. For these reasons, it would have been obvious in the art to use two or three intersecting light beam in the modified device of Gafni in order to accurately determine the distance between the device and human body and since one in the art would have recognized that whether two or three light beams are used, the same desired expected result of enabling one to obtain an accurate distance measurement would have been achieved.

4. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demand (US 4759712) in view of Gafni et al (US 5191896).

- Regarding claim 6, Demand teaches a device for determining thermal sensitivity of nerve sensitive tissue in which a means for producing an air

stream, or pressurized fluid (i.e. air) source is connected to source line (92) (Figure 1, column 5, lines 8-10). It comprises a probe assembly (20) capable of directing air (figure 1) and a sensor (50) within tube (20) for measuring temperature of exiting air stream. Demand doesn't teach his system able to determine a perceived temperature at the measuring point. However, Gafni teaches a threshold sensitivity system wherein a probe is able to adapt temperatures until the stimulus was perceived and record perceived temperature (column 4, lines 39-49). It would have been obvious in view of Gafni to enable Demand's sensor to be able to determine perceived temperature in order to determine a patient's sensory threshold.

- Regarding claim 7, sensor (50) is capable of measuring air temperature (Figure 2).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni and Demand as applied to claim 3 above, and further in view of Servos (US 3995620).

- Regarding claim 8, Gafni and Demand don't teach that the device is capable of adjusting the air stream. However, Servos teaches an airflow testing device with a flow adjust control (17), which adjusts volume of air (Figure 1). It would have been obvious to one having ordinary skill in the art to put the control on Gafni and Demand's device in order to have the correct amount of air for making accurate measurements at different body areas.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni and Demand as applied to claim 10 above, and further in view of Potter (WO 03/000124).

- Regarding claim 11, Gafni and Demand don't teach using light sources in the form of LEDs or laser diodes with intersecting beams at a predetermined spacing from the device. However, Potter teaches a diagnostic temperature probe with pair of LEDs (22) that are positioned to create mutually converging beams (24) at a predetermined distance (page 7, lines 4-7, Figure 1). It would have been obvious in light of Potter to use LEDs on Gafni and Demand's device in order to ensure a desired spacing between the device and the point being measured.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni and Demand, and Potter in view of May et al (US 2002/0108451).

- Gafni teaches a method of measuring sensory threshold which is used in the determination of sensory disorders in which a device is provided to measure thermal sensitivity using a plurality of methods such as method of limits, which is known to be a method of increasing a stimulus is detected or lowering it until no longer detected, thus correlated to a perception of temperature (column 1, lines 35-50). Gafni teaches using a skin temperature sensor (22) to communicate body surface temperature with the computer (figure 1, column 2, lines 50-54). Gafni doesn't teach directing an air stream onto the measurement area. However, Demand

teaches a nerve sensitivity measuring apparatus, which uses pressurized fluid defined to be air which inherently has humidity, temperature, spacing, and flow-rate parameters (column 6, lines 29-32). It would have been obvious in view of Demand to use an apparatus that produces forced air in Gafni's method in order to remove possible influences on perception of using solid object in contact with the test area.

- Further, Gafni teaches monitoring the temperature parameter with a display (82), but doesn't teach monitoring the other parameters. However, Potter, drawn to a measuring probe for a human body, teaches using two intersecting light beam for measuring the distance or spacing between the probe and the human body. May et al. teaches a gaseous mass flow measurement device which measures rate of flow, humidity, and temperature at the emission point [0102]. It would have been obvious in view of Potter and May to monitor all of the properties of Demand's gas in performing Gafni's method in order to keep all other variables constant.

Response to Arguments

8. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENEE DANEGA whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 7:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736